Title: Activities Subject to IRB Review
Standard Operating Procedure: # 7
Department: Human Research Protection Program/Institutional Review Board
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Subject: Activities Subject to the Lawrence Livermore National Laboratory Human Research Protection Program and IRB Review

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Definitions:

LLNL Agent: A person acting on behalf of, and under the direction of LLNL faculty, staff, or students.

Research: A systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge.

> *Systematic Investigation:* A study or examination involving a methodical procedure or plan.
>
> *Generalizable Knowledge:* Conclusions, facts, or principles derived from particulars (e.g., individual subjects or medical records) that are applicable to or affect a whole category (e.g., members of a class, kind, group, or a field of knowledge) and enhance scientific or academic understanding.

Human Subject: A living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction, or (2) identifiable private information

> *Intervention:* includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes
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> *Interaction:* includes communication or interpersonal contact between investigator and subject
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> *Private Information:* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical or school record). In order to meet the above definition, private information must be individually identifiable (e.g., the identity of the subject is known or may readily be ascertained by the investigator or associated with the information) in order for the investigation to constitute research involving human subjects. In general, private information is considered to be individually identifiable when it can be linked to a

specific individual by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person could ascertain the identity(ies) of the individual(s).

Policy:
All of the following research must be reviewed and approved in accordance with these policies prior to initiation of the research if LLNL is "engaged" (as described below) in the research:

Research Involving Human Subjects and Clinical Investigations: All research involving human subjects as described in *Standard Operating Procedure #3, What Is Research Involving Human Subjects?*

Research Involving Death Records: State law requires IRB review of studies using state issued death records (certificates and indices).

I. LLNL is "engaged" in human subjects research if:

1. LLNL employees or agents intervene with living individuals by performing noninvasive or invasive procedures for research purposes (e.g., drawing blood, collecting other biological samples, dispensing drugs, administering treatments, employing medical technologies, using physical sensors, or using other measurement procedures).

2. LLNL employees or agents intervene with living individuals by manipulating the environment for research purposes (e.g., controlling environmental light, sound, or temperature; presenting sensory stimuli; orchestrating environmental events or social interactions; or making voice, digital, or image recordings).

3. LLNL employees or agents interact with living individuals for research purposes (e.g., engaging in protocol-dictated communication or interpersonal contact, conducting research interviews; or obtaining informed consent).

4. LLNL employees or agents release individually identifiable private information, or permit investigators to obtain individually identifiable private information, without the subject's explicit written permission (e.g., releasing patient names to investigators for solicitation as research subjects or permitting investigators to record private information from medical records in individually identifiable form).

5. LLNL employees or agents obtain, receive, or possess private information that is individually identifiable (directly or indirectly through coding systems) for research purposes.

6. LLNL employees or agents obtain, receive, or possess private information that is individually identifiable (directly or indirectly through coding systems) for the purpose of maintaining "statistical centers" for multisite collaborative research.

7. LLNL employees or agents maintain "operation centers" or "coordinating centers" for multi-site collaborative research.

8. LLNL receives direct HHS awards to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

II. LLNL is NOT "engaged" in human subjects research if:

1. LLNL employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information.

   a. If an LLNL employee or agent accesses or uses individually identifiable private information while visiting a non-LLNL research team's institution, the consultants activities become subject to the oversight of the research team's IRB. However, LLNL is still not "engaged" in the research.

   b. Should an LLNL employee or agent obtain "coded" data for analysis at LLNL, LLNL is considered engaged in human subjects research, unless a written agreement unequivocally prohibits the release of identifying codes to the LLNL employee or agent.

2. LLNL employees or agents (i) perform commercial services for the investigators (or perform other genuinely noncollaborative services meriting neither professional recognition nor publication privileges), and (ii) adhere to commonly recognized professional standards for maintaining privacy and confidentiality (e.g., an appropriately qualified laboratory performs analyses of blood samples for investigators solely on a commercial basis).

3. LLNL employees or agents (i) inform prospective subjects about the availability of research; (ii) provide prospective subjects with written information about research (which may include a copy of relevant informed consent documentation and other IRB approved materials) but do not obtain the subjects consent or act as authoritative representatives of the investigators; (iii) provide prospective subjects with information about contacting investigators for information or enrollment; (iv) obtain and appropriately document prospective subjects permission for investigators to contact them.

4. LLNL permits the use of its facilities for intervention or interaction with subjects by research investigators (e.g., LLNL permits investigators to test students whose parents have provided written permission for their participation).

5. LLNL employees or agents release identifiable private information to investigators with prior written permission of the subject.

6. LLNL employees or agents release identifiable private information or specimens to a State or Local Health Department or its agent for legitimate public health purposes within the recognized authority of that Department.

7. LLNL employees or agents release information and/or specimens to investigators in a nonidentifiable form, where such information/specimens have been obtained by the institution for purposes other than the investigator's research (e.g., nursing home employees provide investigators with a data set containing no direct or indirect identifiers through which the identity of the individual subjects could be ascertained—contact the IRB Office for a list of direct versus indirect identifiers).

8. LLNL employees or agents receive information or specimens for research from established repositories operating in accordance with (i) an applicable Federalwide Assurance; (ii) OHRP guidance; and (iii) written agreements unequivocally prohibiting of release of identifying information to recipient investigators.

9. Institutions (or private practitioners) whose clinical staffs provide protocol-related care and/or follow-up to subjects enrolled at distant sites by clinical investigators in OHRP-recognized "Cooperative Protocol Research Programs" (CPRPs).

Examples of Activities That Generally Require IRB Review:

1. Masters Theses/Doctoral Dissertations involving human subjects;
2. Pilot Studies involving human subjects;
3. Clinical Investigations including research to increase scientific understanding about normal or abnormal physiology, disease states or development, and research to evaluate the safety, effectiveness, or usefulness of a medical product, drug, device, procedure, or intervention. Vaccine trials, medical device research, and cancer research are all types of clinical investigation.
4. Behavioral and Social Science Studies such as investigations on individual and group behavior, mental processes, or social constructs. These usually generate data by means of surveys, interviews, observations, studies of existing records, and/or experimental designs involving exposure to some type of stimulus or environmental intervention.
5. Epidemiological Studies such as investigations on health outcomes, interventions, disease states, and conclusions about cost-effectiveness, efficacy, efficiency, interventions, or delivery of services to affected populations. This research may be conducted through surveillance, monitoring, and reporting programs. Other methods may include retrospective review of medical, public health, and/or other records. This includes meta-analysis of multiple case reports and retrospective record reviews that incorporate data collection and analysis.
6. Human Genetic Research such as pedigree studies; positional cloning studies; gene transfer research; longitudinal studies to associate genetic conditions with health, health care, or social outcomes; and gene frequency studies.

Examples of Activities That *May Not* Require IRB Review:

1. Class Projects, Research Practices, and Undergraduate Thesis Projects involving research methodology and course-assigned data collection. These activities generally do not constitute research because they are designed to provide training in research as part of the overall educational mission of a program and are not intended to contribute to new knowledge.
2. Quality Assurance/Quality Improvement Programs that attempt to measure the effectiveness of programs or services, including program evaluations, model curriculum, or needs assessments. Such activities are not typically designed to be generalizable to the larger community and would not be considered research if results will not be compared with other assessments. Those responsible for such projects must be certain that the activities are not human subjects research and should contact the IRB if in question.
3. Case Reports utilizing private identifiable information such as medical information collected from a clinical activity. Case reports are generally carried out by retrospective review of records and highlight a unique treatment, case, or outcome. As the collection and organization of information for such reports usually involves no data analysis or testing of a hypothesis, they do not constitute a systematic investigation. Therefore single case reports would not require IRB review.
4. Research on Institutions or Social Processes when the intent or focus of the research is to gain knowledge of an institution or social process. (e.g., a political party or labor negotiations) and this research is not intended to generate generalizable knowledge about any particular individual or groups of individuals. Often, investigators wish to collect information from individuals about institutions or social processes. Such activities are not considered human subjects research when the focus of the research is not on characteristics of an individual or groups of individuals because the information collected from the informant is not about the informant.

In all cases, investigators should contact the IRB to discuss the research project in question to obtain a determination of the type of IRB review that may be required.

References:

45 CFR 46.102(d,f)
21 CFR 50.3 f
California Health and Safety Codes 102231,125115-125117
OHRP Guidance on "Engagement of Institutions in Research"